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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CIBA VISION CORPORATION
PATENT DEPARTMENT
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EXAMINER

SCHWARTZ, JORDAN MARC

ART UNIT	PAPER NUMBER
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2873

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No. 10/588,088	Applicant(s) EVANS ET AL.	
	Examiner Jordan M. Schwartz	Art Unit 2873	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 13, 14, 17 and 18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14 and 17-18, drawn to a contact lens.

Group II, claim(s) 15-16, drawn to a method of producing a contact lens.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention of Group I has the special technical features of comprising a contact lens movable on the eye between positions in which the lens is positionally stable on the eye in each of the positions and requires a force to be applied to move between the first and second positions; and Group II has the special technical features of defining a first eye shape comprising a spherical sclera and an ellipsoid cornea, rotating the first eye shape in a first direction and rotating the first eye shape in an opposite direction to define eye shapes.

During a telephone conversation with Jian Zhou on June 10, 2008, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14, 17-18. Affirmation of this election must be made by

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applicant in replying to this Office action. Claims 15-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/AU05/00101, filed on January 28, 2005.

Drawings

The drawings are objected to under 37 CFR 1.84 (t) which states "The sheets of drawings should be numbered in consecutive Arabic numerals beginning with "1". Specifically, the presented drawings are labeled from 1-8 and 11-13. Figures labeled as "9" and "10" have not been presented.

The drawings are additionally objected to because they do not indicate figures 1 and 3 as prior art.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures

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appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to because in the “Brief Description of the Drawings” and within the specification, figures 9 and 10 are described, which are absent from the submitted drawings.

Claim Objections

Claims 5, 8, and 12 (and their respective dependent claims) are objected to because of the following informalities:

1. With respect to claim 5, the preamble is not fully amended to properly reflect its singular dependency. The preamble should be amended to exclude the phrase “any one of”;

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2. With respect to claim 8, “shape of back surface” should be corrected to “shape of the back surface”;

3. With respect to claim 12, the semicolon located on the second line should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 (and dependent claim 10) is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for “at least a central part of the back surface of the lens comprises a combination of two concave surfaces, and two points on said concave surfaces may be connected...”, does not reasonably provide enablement for “at least a central part of the back surface of the lens comprises a concave surface or a combination of two such surfaces, and any two points on said concave surfaces may be connected...”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Specifically, all of applicant’s embodiments which disclose two points connecting a straight line that do not pass the interior of the lens disclose the lens having two concave surfaces. None of the embodiments disclose two points connecting a straight line that do not pass the interior of the lens with only a single concave surface. Additionally, *any* two points taken on

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said surfaces disclosed in the application and connected may easily pass through the interior of the lens. Examiner notes that an amendment to the effect such that "...~~any~~ two points on ~~such~~ said concave surfaces..." is enabled by the specification and drawings. Therefore the claimed "any two points" additionally lacks enablement.

Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 11, the claimed "said surfaces" renders the claim vague and indefinite. Specifically, it is not clear if applicant is using the term "said surfaces" to refer to the "front and back surfaces" or to the "major and minor concave surfaces". For purposes of examination the assumed meaning is "wherein said major and minor concave surfaces are combined...".

With respect to claim 12, the preamble frames the claim as a dependant claim while failing to identify the claim on which it depends. The intended dependency is not known rendering the claim vague and indefinite. For purposes of examination it is assumed that claim 12 depends from claim 2.

Claim Rejections – 35 USC §102

The following a quotation of the appropriate paragraph of 35 USC 102 that form the basis of the rejections under this section made in this office action:

A person shall be entitled to a patent unless:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-6, and 9-12 are rejected as anticipated by Kelman (U.S. Pat. # 4,728,182).

As to claim 1, Kelman discloses a contact lens having near vision and distance vision portions (see Col. 2, lines 40-41, "according to this invention there is provided a bi-focal contact lens..."), wherein the lens is movable between two positions (see col. 2, lines 40-51, "comprising a first lens portion...curved to fit the cornea of a patient...and powered for distance vision" and a "second lens portion, integral with the first lens portion, has a posterior surface also curved to fit the cornea and powered for near vision" re the "two positions" and column 4, line 61 to col 5, line 16 re "movable between the two positions"), wherein additionally the lenses are associated with near and far vision magnifications (see col. 2, lines 44-48, "the first lens is powered for...distance vision," col. 2, lines 51-53, "the second lens portion is powered...for near vision), said lens being positionally stable on the eye in each of said positions (see col. 2, line 42, wherein the first lens portion is "curved to fit the cornea" and line 48-49, wherein the second lens portion "is also curved to fit the cornea"), and requiring a force to applied to said lens to move between said first and second positions (see Col. 4, line 61 through col. 5, line 16, "movement of the lens from distance vision to reading visions positions...can be accomplished in a number of different ways...").

As to claim 2, Kelman further discloses a lens with both a front and back surface, wherein the back surface has either one or two major back curve zones which occupy a major portion of the lens back surface (see figs. 2 and 4, wherein

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said curve zones are indicated by 22 and 32, respectively, see also col. 4, lines 13-15, "the rear surfaces 22 and 32 of the two lens segments 20 and 30, while they may be of different diameter are both spherically shaped").

As to claim 3, Kelman additionally discloses a lens wherein at least one (or both) of these surfaces collectively comprise at least 50% of the back surface. Such a feature is inherent within the disclosure as is claimed by applicant, as applicant does not claim any particular structure which corresponds with said back surfaces. Such a feature is particularly inherent when such a claim is phrased in the disjunctive either/or phrasing (see applicant's claim 2) and is absent of any corresponding structure. Furthermore, any portion of the back surface of figs 2 or 4 greater than 50% can be considered as "major portion/s" since applicant is not disclosing any structure to distinguish major portion/s from minor portions.

As to claim 4, said peripheral edge is also disclosed within the Kelman disclosure and due to the absence of any structure as claimed to differentiate the back curve zones, can be interpreted within the disclosure as inherent within the Kelman disclosure as the peripheral edge may simply be any section not included within the center of the Kelman lens which take up at most 49% of the lens.

Claim 5 is anticipated by the Kelman disclosure. As mentioned *supra*, claim 2 is anticipated by Kelman, and Kelman further discloses major and minor concave surfaces (see figure 1, denoted by items 22 and 32, see also col. 3,

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lines 43-45) i.e. any portion of the back surface can inherently be considered as either a "major portion" or a "minor portion".

Claim 6 is anticipated by Kelman, as the Kelman disclosure further recites a blending zone as recited within the application without any structure associated with it. Kelman discloses two vision zones which are connected via a blending zone (see figures or 3, wherein any part of the lens which connects the far vision portion 20 and near vision portion 30 can be considered a 'blending zone').

Claim 9 (as per the assumed meaning above) discloses two points that may be connected without passing to the interior of the lens (see figure 2 and 4, wherein points on the exterior and on axes a and b or within said axes).

With respect to claim 10, Kelman discloses the lens as according to claim 9, and further discloses two concave surfaces which cover the entire back portion of the lens excluding the peripheral edge thereof, absent any defining structure as claimed of said peripheral edge (Figures 2 and 4).

With respect to claim 11 Kelman discloses major and minor concave surfaces, which are combined with a narrow blending zone (see figures 1 and 3, wherein the connecting portion on the concave surface of lenses 20 and 30 is a "narrow blending zone").

With respect to claim 12, Kelman discloses two concave surfaces on the rear surface of the lens, wherein one lens is smaller in size than the other lens (see figs. 1, 3, 5, 6, and 7). In such a scenario, the larger lens is positionally more stable and it takes a greater force to move from the large lens to the small lens, and a smaller force to move the lens from the smaller surface to the larger one.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman in view of Lindacher (U.S. Pat. #7,004,585).

Kelman discloses as is set forth above including disclosing that the lens concave surface has two different zones with a blending portion between (Figures 2 and 4, portions 22 and 32 with the section between as a blending zone) but does not specifically disclose this blending zone conforming to a continuous second derivative.

Lindacher teaches of a contact lens having two different zones with a blending zone between (abstract) can further have the blending portion conforming to a continuous second derivative for the purpose of providing a smooth transition between the zones (column 4, lines 3-19). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the back surface of Kelman so as to conform to a continuous second derivative since Lindacher teaches that a contact lens having two different zones with a blending zone between (similar to Kelman) can further have the blending portion conforming to a continuous second derivative for the purpose of providing a smooth transition between the zones. Furthermore, the

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examiner takes Judicial Notice that “infinitely continuous differentiable functions” are well known continuous second derivative functions for the purpose of providing smooth transitions. Therefore, it further would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the continuous second derivative surface of Kelman as modified by Lindacher as being formed of an infinitely continuous differential function since such functions are well known types of second derivative function used to provide smooth transitions.

Allowable Subject Matter

Claims 13, 14, 17 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. With respect to the allowable subject matter, none of the prior art either alone or in combination disclose or teach the claimed combination of limitations to warrant a rejection under 35 USC §§102 or 103. Specifically, in reference to these claims, none of the prior art or in combination disclose or teach the claimed lens, specifically including, as the distinguishing feature in combination with the other limitations, the limitation of the lens adapted to change in cross sectional shape in moving between the claimed first and second positions.

Examiner's Comments

Due to the broadness of the claims, many other references would have either read on or made obvious a number of the above rejected claims, however, such rejections would have been repetitive.

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For example, most bifocal contact lenses that move between first and second positions due to the movement of the eyelid would have read on at least claim 1. Specifically, the eyelid movement being applied to the lens can be considered as "a force applied to the lens to move between the first and second positions" (such as Lindacher patent number 7,004,585, see figs 2A and 2B).

Additionally, Mandell, publication number 2003/0016331, and Morstad patent number 5,141,301, are being cited herein to show contact lenses that also would have read on or made obvious a number of the above rejected claims, however, such rejections would have been repetitive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jordan M. Schwartz whose telephone number is (571) 272-2337. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ricky Mack can be reached on (571) 272-2333. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jordan M. Schwartz
Primary Examiner
Art Unit 2873
July 2, 2008

/Jordan M. Schwartz/
Primary Examiner, Art Unit 2873